

Remarks**Rejections of the claims**

In the May 19, 2011 Office Action, the Office stated that:

claims 81-83, 90-100, 103-104 and 107-111 were rejected under 35 U.S.C. §112, first paragraph;

claims 81-83, 90-100, 103-104 and 107-111 were rejected under 35 U.S.C. §112, second paragraph;

claims 81-83, 90-96, 99, 103-104 and 111 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,397,591 to Kyle *et al.* (hereinafter Kyle) and Barclay (U.S. Patent No. 5,698,244, hereinafter Barclay) in view of (U.S. Patent No. 5,427,783 to Gierhart (hereinafter Gierhart) and in further view of U.S. Patent No. 5,989,600 to Nielson (hereinafter Nielson);

claims 97-98, 100 and 109-111 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle and U.S. Patent No. 5,698,244 to Barclay (hereinafter Barclay) in view of Gierhart, Nielson, Japanese Patent No. 2002-253140 and Japanese Patent No. 6011025; and

claims 107-108 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle and Barclay in view of Gierhart and in further view of U.S. Patent No. 6,075,058 or JP 06070698.

These rejections are respectfully traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

Rejection under 35 U.S.C. §112, first paragraph

According to the Office, claims 81-83, 90-100, 103-104 and 107-111 do not meet the enablement requirement. Applicant vigorously disagrees. The claims describe an animal that is fed a certain type diet. The application provides sufficient support for preparation of the feed which is fed to an animal. The claims recite a product by process and the process includes a specific feed that is easily recreated. An aquatic animal being fed this diet is enriched in DHA and carotenoids. The specification provides ample guidance for testing an animal to determine the levels of the specific components.

Applicants remind the Office that some experimentation may be required as long as it is not undue. In *PPG Indus., Inc., v. Guardian Indus. Corp.*, 27 USPQ2d 1618, 1623 (Fed. Cir. 1996), the court stated that even where some experimentation is necessary to reduce an invention to practice, the enablement requirement is satisfied where: (1) the experimentation is routine; or (2) the specification provides “a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.” Applicants' specification meets these requirements. As such, applicants request the withdrawal of this rejection under section 112, first paragraph .

Rejection under 35 U.S.C. §112, second paragraph

Claims 81-83, 90-100, 103-104 and 107-111 were rejected under 35 U.S.C. §112, second paragraph for being indefinite. Applicants have amended the claims, thereby obviating this rejection. Applicants request the withdrawal of this rejection.

Rejections under 35 U.S.C. §103(a)

1. Claims 81-83, 90-96, 99, 103-104 and 111 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle and Barclay in view of Gierhart and in further view of Nielson. Applicants insist that the proposed combination does not in any way teach or suggest the presently claimed invention.

According to the Office, on page 12 of the Office Action, all 3 ingredients or elements have been established by prior art for the same purpose, feeding aquatic animals, thereby rendering their use together obvious. Applicants do not agree with the speculation of the Office.

Kyle teaches the production of DHA from algae and but never considers the inclusion of a feed that also include a carotenoid. The Kyle reference teaches the use of the biomass as a feed for aquaculture.

Barclay discloses a biomass but it is impossible to determine the level of DHA in the feed, noting that it is considered to be only a feed additive. One does not know whether the additional feed contains animal material, whether it contains high or low levels of DHA, or whether the food additive is in addition to conventional feed. Animals cultivated using the feed of Barclay *may* result in a similar animal to what is claimed. Regarding the obviousness rejection, the Court's decision in *In re Spormann*, 150 USPQ 449 (CCPA 1966), bears directly on point:

“The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown”

Here the amount of DHA was unknown. Therefore, how could a skilled artisan make any modification while arriving at an invention that possesses the heretofore unknown characteristic. While it is possible that, serendipitously, the feed would have such a feature, serendipity is not a valid basis for asserting obviousness.

To overcome the shortcomings of Kyle and Barclay, the Office has introduced the teaching of Gierhart. Gierhart describes a bacteria that can produce zeaxanthin but only if a sufficient nutrient medium is used for culturing the bacteria. Neilsen is no longer relevant to the amended claims.

Notably, none of the references, alone or in combination makes any suggestion of combining wherein the inclusion of a DHA-enriched phospholipid extracts from algae, results in an unexpected increased bioavailability of carotenoid pigments.

Applicants submit that there is no teaching or suggestion for the specific components of the presently claimed invention in the multiplicity of references cited by the Office. Further, the Office has set forth an insufficient standard for an "obvious to combine" rejection under § 103(a) based on the various references included in the § 103 rejection. The fact that particular references disclose the use a DHA component for inclusion in compositions does not automatically make the reference obvious to combine with other compositions containing a carotenoid. *KSR Intl Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Rather, the Office bears the burden of identifying a reasoned rationale as to why a skilled artisan would have had any reasonable expectation of success or inclination to combine prior art components to arrive at the present invention. *Id.* at 1741-42. As the Supreme Court clearly articulated, merely demonstrating that each element of a claimed combination is known in the prior art does not constitute obviousness. *Id.* at 1741.

The Office's attention is directed to the Federal Circuit's decision in *Environmental Designs v. Union Oil Co. of Cal.*, 218 USPQ 865 (Fed. Cir. 1983), where the court stated:

“ That all elements of an invention may have been old (the normal situation), or some old or some new, or all new, is however, simply irrelevant. Virtually all inventions are

combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art.”

Thus, the fact that isolated elements of an invention are “disclosed” in the prior art is alone insufficient. The test is not whether isolated “elements” are known, but rather whether the subject matter of the invention “as a whole,” in light of all the teachings of all the cited references in all of their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. Notably, the Office seems to be merely reinterpreting the prior art in light of applicants’ disclosure, in order to reconstruct applicant’s claimed invention, but without any instructional or motivating basis in the references themselves.

In conclusion and in light of the above amendments and discussion, Applicants submit that the Office has not met its burden of establishing a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejection of the pending claims for obviousness be withdrawn.

2. Claims 97-98, 100 and 109-111 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle and Barclay in view of Gierhart, Nielson, Japanese Patent No. 2002-253140 and Japanese Patent No. 6011025.

Applicants have already shown that the combination of Kyle, Barclay, Gierhart and Nielson does not teach or suggest the presently claimed invention. The addition of the two Japanese references does not rectify the shortcomings of the first four references.

Applicants assert that Japanese Patent Nos. 2003-0253140 and 60110250 do not cure the deficiencies of the earlier cited reference with respect to independent claim 81, from which all claims depend. Namely, the Japanese patents do not teach cultivating an aquatic animal by using feed that is totally vegetarian and does not include fish oil or fish meal. Instead, as clearly stated at the top of column 3 of the JP 2003-0253140, the feed included fish meal such as cuttlefish or krill. Thus, even if the JP secondary references teach the use of taurine, there is not sufficient disclosure for all the elements of claim 1.

It is very important to note that applicants specifically included specific carotenoids from very specific sources because they did not want to add to the level of astaxanthin due to the negative effects of increased levels of astaxanthin as stated in paragraph [0033] of the published application. Applicants surprising found that the use of the sources, as recited in claim 81, did not result in complete conversion

of the added carotenoids into astaxanthin. This is very important because the carotenoid level was increased but without the negative effects caused by increased levels of astaxanthin.

As previously stated, that which is unknown cannot possibly be obvious and none of the cited references recognize the importance of the specific sources of carotenoids. Thus, claims 97, 98, 100, and 109-111 distinguish over the prior art for at the least reasons discussed previously. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 97, 98, 100, and 109-111.

3. Claims 107-108 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle and Barclay in view of Gierhart and in further view of U.S. Patent No. 6,075,058 or JP 06070698. This rejection has been obviated due to the cancellation of such claims.

Petition for Extension and Fees Payable

Applicants petition for a one month extension and the fee of \$65.00 is being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Sayala, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Sayala is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

/mariannefuierer/

Marianne Fuierer
Reg. No. 39,983
Attorney for Applicant

Moore & Van Allen, PLLC
Telephone: (919) 286-8000
Facsimile: (919) 286-8199